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09/646,043 10/25/00 HAKALEHTO

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EXAMINER

SHANNAN-SHAH, K

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/646,043

Applicant(s)

HAKALEHTO, EINO ELIAS

Examiner

Khatol S Shahnan-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2000 and 16 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 October 2000 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

1. Applicant's preliminary amendments, received 9/13/2000 and 3/16/2001, papers # 1 and 8 are acknowledged.

Claims 5, 7, 8, 11, and 13 were amended. Specification pages 1 and 6 (lines 20-27) were amended.

2. Information Disclosure Statement paper # 6 received 12/13/2000 is acknowledged.

3. Currently claims 1-13 are pending and under consideration.

Abstract

4. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b).

An abstract on a separate sheet is required.

Drawings

5. The drawings are objected to by the Draftsperson under 37 CFR 1.84 or 1.152. See attached form PTO 498.

6. The drawings are objected to by the Examiner as failing to comply with 37 CFR 1.84(p)(5) because they are not explained in the description. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d) Correction is required.

Priority

7. Complete priority statement is missing from specification:

This application filed under former 37 CFR 1.62 lacks the necessary reference to the prior application(s). A statement reading " This is a U.S.C. 371 of Application of PCT/FI99/00192 filed on March 15,1999 and claims priority to Finnish application No. 980571, filed on March 13, 1998" should be entered following the title of the invention or as the first sentence of the

specification. Also, the current status of the parent nonprovisional application(s) should be included. The preliminary amendment received on 09/13/2000 does not address the complete above statement. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, until proper corrections are made.

Specification Informalities

8. The disclosure is objected to because of the following informalities:

Appropriate corrections are required.

A brief description of drawings is not mentioned in the description. A reference in the specification to the brief description of the drawing(s) is required as set forth in 37 CFR 1. 74

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-2 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1 and 2 recite the phrases "bacteria are detected from their cultivation medium clearly prior to the peak of the population growth" and "the microbial antigens are detected directly after the stationary phase". These encompass any bacteria and any microbial antigen. However the specification only mentions two strains of Salmonella with no explanation to the peak of their population growth or the period after their stationary phase (see example 1, page 6).

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In example 4 applicant mentions the use of RVS broth as growth medium (page 4, line 9). In the same line he also mentions that the plate cultures were started simultaneously with ELISA measurements, it's not clear which medium was used to plate the organism and how bacterial densities were measured. The specification fails to provide essential information and steps. Therefore, one skilled in the art could not make/and or use the invention without undue experimentation.

Claim 11 recites that "the microbes are incubated prior to the immunological detection in their optimal growth temperature". This encompasses any microbe. However the specification discloses only two strains of Salmonella and two different temperature (+ 37°C and + 43°C). It is well known in the art that different microbes has different optimal growth temperature and the specification fails to provide further guidance in this regard. Therefore, one skilled in the art could not make/ and or use the invention without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1- 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "clearly prior to the peak of population growth" in claims 1 is not clear, which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the invention.

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The phrase "directly after the stationary phase" in claims 2 is not clear, which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the invention.

. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 7 is rejected under U.S.C. 102(b) as being anticipated by Boyd et al. (Journal of Bacteriology Vol. 181, No. 4, Feb 1999).

Claim 7 recites SEQ ID NO: 1. An amino acid sequence related to Salmonella fimbrial proteins.

Boyd et al. disclosed the same sequence from fimbrial proteins of Salmonella. page 1302 (fim genes). And residues 41 to 58 (see accession # Q9X3T3 sequence search report).

12. Claim 7 is rejected under U.S.C. 102(b) as being anticipated by Rossolini et al. (FEMS Microbiology Letters Vol. 114, Sep. 1993).

Claim 7 recites SEQ ID NO: 1. An amino acid sequence related to Salmonella fimbrial proteins.

Rossolini et al. disclosed the same sequence from fimbrial proteins encoded by Salmonella fim I gene (pages 262-264) . And residues 65 to 82 (see accession # P37920 sequence search

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report).

13. Claim 7 is rejected under U.S.C. 102(b) as being anticipated by Rossolini et al. (FEMS Microbiology Letters Vol. 114, Sep. 1993).

Claim 7 recites SEQ ID NO: 1. An amino acid sequence related to Salmonella fimbrial proteins.

Rossolini et al. disclosed the same sequence from Salmonella typhi fim A fimbrial protein residues 65 to 82 (see accession # S20682 sequence search report).

14. Claims 1-13 are rejected under U.S.C. 102(b) as being anticipated by Thorns, C. J. et al. (US Patent Number 5,510,241).

Claims 1-13 are drawn to a method for detection of Salmonella fimbrial antigens in a in an enrichment medium which enhances expression of fimbrial antigens.

Thorn et al. disclose a method for testing for the presence of Salmonella species expressing fimbrial antigens, which have been grown on a selected medium. (see title and abstract and claims).

They used a variety of liquid and solid media (see column 2, lines 25-65) and various temperature ranges from 22°C to 60° C (see columns 5 and 6). They also used direct binding and indirect ELISA methods. They too used an isolated peptide comprising from Salmonella fimbrial antigen (SEQ ID 1) see claims 30 and 31 and columns 26-28.

Since the office does not have the facilities for examining and comparing applicants' method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i. e., that the method of prior art does not possess the same material structure and functional characteristics of the

claimed method). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

15. Claims 1-13 are rejected under U.S.C. 102(b) as being anticipated by Thorns, C. J. et al. (WIPO Patent Number WO92/06197).

Claims 1-13 are drawn to a method for detection of Salmonella fimbrial antigens in a in an enrichment medium which enhances expression of fimbrial antigens.

Thorn et al. disclose a method for testing for the presence of Salmonella species expressing fimbrial antigens, which have been grown on a selected medium. (see title and abstract, and claims specially claims 1, 4 and 6).

They used a variety of liquid and solid media (see pages 6-9) and various temperature ranges from 22°C to 60° C (see pages 9-10). They also used direct binding and indirect ELISA methods (see pages 37-39). They too used an antibody produced against Salmonella fimbrial antigen (see claim 4 and pages 13-14). They even produced a test kit for their method (see claim 15).

Additional art cited, but not used in this office action:

1. Thorns, C.J. et al. , Journal of Clinical Microbiology , Vol.34, No. 4, pp. 792-797, April 1996.
2. Sojka et al. , Veterinary Microbiology, Vol. 48, pp. 207-221, 1996.
3. Sojka et al. , Veterinary Microbiology, Vol. 59, pp. 157-174, 1998.
4. Dibb-Fuller et al. , Letters in Applied Microbiology, Vol. 25, pp. 447-452, 1997.

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Conclusion

16. No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30 AM - 4 PM from Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah 6/29/01

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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Rodney P Swartz
RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER